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Dockets Management Branch (HFA-205)
Docket No. 98N-1265
Food and Drug Administration
5600 Fishers Lane
Rockville, MD. 20857

I OPPOSE THE DRAFT M.O.U. being proposed by the FDA. In particular, I OBJECT to the definition of "inordinate amount" which restricts the availability and the right to obtain medically necessary compounded medications by limiting the number of prescriptions that can be shipped across state lines from specialized compounding pharmacies.

Deborah A. Nicholas
Signature

5/16/99
Date

I do not support restricting the availability of individually compounded medication.

As a certified nurse practitioner as well as a patient, I have been using *individually compounded medications* for many years to relieve my various menopausal symptoms, without the many side effects that synthetic hormones cause my body to experience.

It has made the quality of my life superb and symptom free.

I object to the definition of "inordinate amount" in your MOU. I feel that this would severely compromise the quality of my medical care by restricting my ability to obtain the medication that is prescribed by my doctor. I need these hormones to live a life that is free from hot flashes, mood swings and osteoporosis and atrophic vaginitis.

Compounded medications are **necessary** for my health and wellbeing.

Specialty pharmacies provide medication that I am not able to get at commercial or most local pharmacies. Please let me continue to obtain these compounds at my out of state pharmacy.

Thank you.

98N-1265

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